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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	MARKWELL-040	3546

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/447,227

Applicant(s)

SHULTS ET AL.

Examiner

Robert L. Nasser

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-42, 48, 49 and 54-87 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 33-42, 48, 49 and 54-87 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/17/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

The examiner notes that new art was discovered when examining some of applicant's other cases. As such, this application has been withdrawn from issue and the following non-final rejection applied.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-36, 38-42, 48, 49, 54-58, 62-65, 70-73, 76-79, and 85-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al WO 92/13271. Rhodes shows a device in figure 2 including a housing that houses a sensor 30, 32 with an interface tip 36, with a distal first domain, i.e. surgical Dacron (polyester) fabric (see page 17 at the top) to support tissue ingrowth, a second domain, the outer membrane which is impermeable to macrophages (see page 7, lines 30-31 and pages 19+), which is made from silicone (page 22, line 16), a sensing membrane containing an enzyme (see page 7) lines 31 and 32) and a third layer that is an electrolytic phase, between the sensing layer and the sensor (see pages 7-8). Rhodes further teaches implanting the device wholly in a patient so as to elicit a foreign body capsule response, where the tip is anchored by means of a capsular attachment layer, the Dacron coating on the sides and bottom of the device. Claim 35 is rejected in that there is further an angiogenic layer, screen 46 treated with a angiogenesis factor. Claim 36 is rejected in that Dacron is non-smooth. Claim 38 is rejected for the reasons given above, noting that the layer 46

is a vascularization promoting layer. Claim 42 is rejected in that the device includes a transmitter for transmitting data to the exterior of the body(see page 15, line 9). Claims 48 and 49 are rejected in that the enzyme used is glucose oxidase. With respect to claims 56-58, it is the examiner's position that given that the device has the same structure as the claimed invention, it would measure glucose accurate for the time periods. Claim 62 is rejected in that the first domain stabilizes over time. Claims 70-72, and 76-78 are rejected for the reasons given above. Claim 85 is rejected in that the Dacron layer extends across a top surface of the device (depending on the orientation) and anchors the device in place.

Claims 33, 34, 36-42, 48, 49, 54-56, 59, 62-65, 70, 73, 76-79, 85-87 are rejected under 35 U.S.C. 102(b) as being anticipated by the Gilligan et al article entitled "Evaluation of a Subcutaneous Glucose Sensor out to 3 months in a dog model." Gilligan in figure 1 shows a device having a housing, a first domain, the Dacron Velour layer on the top surface in the figure, a second domain – the bioprotective membrane, a sensing membrane including glucose oxidase, an electrolytic phase, i.e. electrolyte, and a sensor. Gilligan teaches a method of monitoring glucose by implanting the device for up to 3 months and explanting it after the time is up. Gilligan further teaches having a wireless transmitter inside the device. In addition, the Dacron layer on the sides and bottom of figure 1 is a capsular attachment layer and a vascularization promotion layer, which serve to anchor the device in place.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3736

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al in view of the Gilligan et al article entitled "Evaluation of a Subcutaneous Glucose Sensor out to 3 months in a dog model." Gilligan further teaches that the Dacron jacket can be made from a Dacron velour. Hence, it would have been obvious to modify Rhodes to use such a layer, as it is merely the substitution of one known material for another.

Claims 59-61, 66-69, 73-75, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al. With respect to claims 59-61 and 73-75, the examiner takes official notice that it is known to explant the device when the useful life of the device is over. With respect to claims 66-69 and 80-83, the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Rhodes to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 59-61, 66-69, 73-75, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilligan et al. With respect to claims 59-61 and 73-75, the examiner takes official notice that it is known to explant the device when the useful life of the device is over. With respect to claims 66-69 and 80-83, the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would

have been obvious to modify Gilligan et al to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilligan et al in view of Allen et al 5322063. Allen et al shows a device where the sensor interface extends out from the housing. As such, it would have been obvious to modify Gilligan to have the interface extend outwardly from the housing, as it is merely the substitution of one known configuration for another.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner



ROBERT L. NASSER
PRIMARY EXAMINER